IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH

NORTHERN DIVISION

ANNA ELKINS, Individually, as Heir to and on behalf of the Estate of LISA JOY ELKINS-REESE, Deceased, Plaintiff, vs. MYLAN LABORATORIES, INC., n/k/a MYLAN INC.; MYLAN PHARMACEUTICALS, INC.; and MYLAN TECHNOLOGIES, INC., Defendants.	MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS Case No. 1:12-CV-255 TS

This matter is before the Court on Defendants' Motion to Dismiss. For the reasons discussed below, the Court will grant the Motion in part and deny it in part.

I. BACKGROUND

Plaintiff Anna Elkins is the mother of Lisa Joy Elkins-Reese (the "Decedent") and the duly appointed personal representative of Decedent's estate. This suit arises out of the death of Decedent due to the alleged wrongful conduct of Defendants. Specifically, Plaintiff alleges that

Decedent was prescribed a Mylan fentanyl transdermal system patch (a patch that releases a certain level of fentanyl into the blood of the patient), that she was wearing one of Defendants' patches at the time of her death, and that the cause of Decedent's death was drug toxicity with fentanyl.

Based on these facts, Plaintiff brings claims for strict products liability (with subclaims for manufacturing, marketing defect, design defect, and misrepresentation), negligence, negligent misrepresentation, breach of express warranty, breach of implied warranty of fitness, breach of implied warranty of merchantability, and gross negligence and intentional misconduct. Plaintiff seeks various damages, including punitive damages.

Defendants seek dismissal of all of Plaintiff's claims, arguing that all of Plaintiff's failure to warn claims are preempted, Plaintiff's claim for punitive damages is invalid, Plaintiff's design defect claim is foreclosed by Utah precedent, and Plaintiff's remaining claims fail to meet the relevant pleading standards. Plaintiff opposes Defendants' Motion, but concedes that her claims for breach of express warranty and breach of implied warranty for fitness should be dismissed. Plaintiff further requests that any dismissal be done without prejudice to allow for amendment after discovery.

II. MOTION TO DISMISS STANDARD

In considering a motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6), all well-pleaded factual allegations, as distinguished from conclusory allegations, are accepted as true and viewed in the light most favorable to Plaintiff as

the nonmoving party.[1] Plaintiff must provide "enough facts to state a claim to relief that is plausible on its face,"[2] which requires "more than an unadorned, the-defendant-unlawfully harmed-me accusation."[3]

"A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'"[4] "The court's function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted."[5] As the Court in *Iqbal* stated,

> only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not show[n]—that the pleader is entitled to relief.[6]

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[1] *GFF Corp. v. Associated Wholesale Grocers, Inc.*, 130 F.3d 1381, 1384 (10th Cir. 1997).

[2] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007).

[3] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[4] *Id.* (quoting *Twombly*, 550 U.S. at 557) (alteration in original).

[5] *Miller v. Glanz*, 948 F.2d 1562, 1565 (10th Cir. 1991).

[6] *Iqbal*, 556 U.S. at 679 (alteration in original) (internal quotation marks and citations omitted).

When considering the adequacy of a plaintiff's allegations in a complaint subject to a motion to dismiss, a district court not only considers the complaint, but also "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice."[7] Thus, "notwithstanding the usual rule that a court should consider no evidence beyond the pleadings on a Rule 12(b)(6) motion to dismiss, '[a] district court may consider documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity.'"[8]

III. DISCUSSION

A. FAILURE TO WARN

Defendants first argue that all of Plaintiff's failure to warn claims must be dismissed based on the recent Supreme Court case of *PILVA, Inc. v. Mensing*.[9] The Court in *Mensing* considered whether state tort claims based on an alleged failure to provide adequate warning labels were preempted by the federal regulations applicable to generic drug manufacturers. The Court held that they were.

Federal law requires generic drug manufacturers to use the same labeling as their brand-name counterparts. Because of this requirement, the Court in *Mensing* found that generic drug manufacturers could not simultaneously comply with the federal sameness requirement and any

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[7] *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (citing 5B WRIGHT & MILLER § 1357 (3d ed. 2004 and Supp. 2007)).

[8] *Alvarado v. KOBTV, LLC*, 493 F.3d 1210, 1215 (10th Cir. 2007) (quoting *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002)).

[9] 131 S. Ct 2567 (2011).

different labeling requirements that state tort law may require. "If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. . . . Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same."[10] Based on this impossibility, the Court held that state law claims based on an alleged failure to provide adequate warning labels were preempted.

In this case, it is undisputed that Defendants are the manufacturers of a generic product. Thus, they are subject to the federal sameness requirement. As a result, any state law claims sounding in failure to warn are preempted under *Mensing*. The majority of Plaintiff's claims contain some sort of failure to warn component. Based on *Mensing*, these claims are preempted.

Plaintiff makes two arguments in opposition to Defendants' Motion to Dismiss her failure to warn claims. First, Plaintiff argues that Defendants could have avoided liability by simply stopping the sales of their product. The Supreme Court rejected this argument yesterday in *Mutual Pharmaceutical Co., Inc. v. Bartlett*.[11] Therefore, the fact that Defendants could have withdrawn their product from the market does not save Plaintiff's failure to warn claims.

Plaintiff also relies on the recent Sixth Circuit case of *Fulgenzi v. PLIVA, Inc*.[12] In that case it was alleged that the manufacturer of a generic drug failed to update its label after the brand-name manufacturer strengthened the warnings on its label. The court held that the

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[10] *Id*. at 2578.

[11] ---S. Ct.---, 2013 WL 3155230 (June 24, 2013).

[12] 711 F.3d 578 (6th Cir. 2013).

manufacturer could have updated its label and had a duty under federal law to do so. Therefore, compliance with federal law and state tort law was not an impossibility and *Mensing* did not require dismissal.

Plaintiff argues that she should be given the opportunity to re-plead her claim to take advantage of this "exception." In this case, there are no allegations that Defendants failed to update their label or that the Decedent's injuries resulted from that failure to update.[13] Therefore, the Court will deny Plaintiff's request at this time. If, however, Plaintiff discovers facts that would support such a claim, she could seek leave to file an amended complaint.

Based on the above, the Court finds that all of Plaintiff's claims relating to a failure to warn are preempted and must be dismissed.

B. PUNITIVE DAMAGES

Plaintiff brings a claim for punitive damages. Defendants argue that Plaintiff's punitive damages claim is invalid under Utah law and preempted.

Utah law generally prohibits an award of punitive damages based on harm allegedly caused by an FDA-approved drug.[14] However, there is an exception to this general rule "if it is shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug

[13]*See id*. at 588 (noting that plaintiff would have to prove that the failure to update proximately caused her injuries).

[14]Utah Code Ann. § 78B-8-203(1).

Administration under its regulations, which information was material and relevant to the claimant's harm."[15]

In *Buckman Co. v. Plaintiffs' Legal Committee*,[16] the Supreme Court held that state law claims based on an alleged fraud on the FDA were impliedly preempted by federal law. In *Buckman*, the plaintiffs alleged that a medical device manufacturer made fraudulent representations to the FDA in the course of obtaining approval for its product. The Court held that state law claims based upon these alleged misrepresentations were impliedly preempted by federal law. "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."[17]

> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.[18]

Dispute over the scope of *Buckman* has resulted in a circuit split, and even a split within this District. In *Stanley v. Mylan*,[19] this Court held that *Buckman* did not bar punitive damages

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[15]*Id*. § 78B-8-203(2).

[16]531 U.S. 341 (2001).

[17]*Id*. at 350.

[18]*Id*. at 353.

[19] 2010 WL 3718589 (D. Utah Sept. 17, 2010).

claims under Utah Code Ann. § 78B-8-302. Other Judges within this district, have reached the opposite conclusion.[20]

Having reviewed the arguments of the parties, the Court finds that its conclusion in *Stanley* is no longer supportable, especially in light of the Supreme Court's recent rulings in *Mensing* and *Bartlett*. Therefore, the Court will overrule its decision in *Mylan* and hold that Plaintiff's punitive damages claim is barred.

C. DESIGN DEFECT

Defendants next argue that Plaintiff's strict liability design defect claim must be dismissed under Utah law. Plaintiff has not responded to this argument.

In *Grundberg v. Upjohn Co.*, the Utah Supreme Court interpreted comment (k) of the Restatement (Second) of Torts § 402A as eliminating a strict liability cause of action for FDA-approved drugs based on design defects.[21] Based on this clear authority, Plaintiff's design defect strict liability claim must be dismissed. However, Plaintiff's remaining strict liability claims, based on manufacturing flaws and inadequate warnings, are not barred by comment (k),[22] though at least portions of those claims are preempted by *Mensing*.

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[20]*Pierce v. Mylan Labs., Inc.*, 2011 WL 2650726, at *1 (D. Utah May 18, 2011); *Grange v. Mylan Labs., Inc.*, 2008 WL 4813311, at *7 (D. Utah Oct. 31, 2008).

[21]813 P.2d 89, 99 (Utah 1991).

[22]*Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922 (Utah 2003).

D. REMAINING CLAIMS

In addition to the arguments discussed above, Defendants seek dismissal of Plaintiff's remaining claims because they fail to meet the applicable pleading standards.

1. Strict Products Liability

Plaintiff brings various claims for strict products liability. "Products liability always requires proof of a defective product, which can include 'manufacturing flaws, design defects, and inadequate warnings regarding use.'"[23] "A plaintiff must prove three elements to succeed in a strict products liability suit: (1) that the product was unreasonably dangerous due to a defect or defective condition, (2) that the defect existed at the time the product was sold, and (3) that the defective condition was a cause of the plaintiff's injuries."[24]

a. Manufacturing Defect

Plaintiff alleges that Defendants' product was unreasonably dangerous due to a defect or defective condition, namely that it was defective because it gave the Decedent a much higher dose of fentanyl than a properly functioning patch should have given. Plaintiff further alleges that the defect existed at the time it was sold and that it was a proximate and/or producing cause of the Decedent's death and Plaintiff's damages.

Plaintiff's allegations fall short of what is required to state a manufacturing defect claim. Plaintiff fails to allege any specific manufacturing defect of which Defendants' product suffers.

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[23] *Bishop v. GenTec Inc.*, 48 P.3d 218, 225 (quoting *Grundberg*, 813 P.2d at 92).

[24] *Niemela v. Imperial Mfg., Inc.*, 263 P.3d 1191, 1195 (Utah Ct. App. 2011) (quotation marks and citation omitted).

Rather, Plaintiff appears to argue that, because Decedent's cause of death was drug toxicity with fentanyl, there must have been a manufacturing defect. These allegations are insufficient. Therefore, this claim will be dismissed without prejudice.

b. Marketing Defect

Plaintiff further alleges that Defendants' product was defective because it lacked adequate and/or proper warnings and instructions. For the reasons discussed above, this claim is preempted under *Mensing*. Further, Plaintiff fails to describe what warnings were inadequate and/or what proper warnings or instructions should have been included. Additionally, while Plaintiff alleges that the marketing defects were the proximate and/or producing cause of Decedent's death and Plaintiff's damages, she does not expand on this. These allegations are insufficient to withstand dismissal. Therefore, this claim will be dismissed with prejudice.

c. Design Defect

For the reasons set forth above, Plaintiff's strict liability design defect is barred under Utah law and will be dismissed with prejudice.

d. Misrepresentation

Finally, Plaintiff brings a strict liability for misrepresentation claim. Such a claim is not recognized under Utah law and is merely a reiteration of her preempted failure to warn claim. Therefore, it will be dismissed with prejudice.

2. Negligence

In addition to strict liability claims, Plaintiff brings a claim for negligence. "In a products liability case, the plaintiff must . . . prove that there was a duty owed by the defendant to the plaintiff, that the duty was breached and that the conduct complained of was the cause in fact of the injury."[25]

The allegations in Plaintiff's Complaint, though largely conclusory and devoid of factual development, are sufficient to withstand dismissal. Plaintiff sufficiently alleges that Defendants owed her and the Decedent a duty, describes the various ways in which Plaintiff believes Defendants breached that duty, and that those breaches caused the Decedent's death and Plaintiff's injuries. Therefore, Defendants' Motion will be denied as to Plaintiff's negligence claim, except those negligence claims based on a failure to warn.

3. Negligent Misrepresentation

The tort of negligent misrepresentation "provides that a party injured by reasonable reliance upon a second party's careless or negligent misrepresentation of a material fact may recover damages resulting from that injury when the second party had a pecuniary interest in the transaction, was in a superior position to know the material facts, and should have reasonably foreseen that the injured party was likely to rely upon the fact."[26]

Plaintiff's negligent misrepresentation claim is based on an alleged failure to warn by Defendants. Such a claim is preempted under *Mensing* and will be dismissed with prejudice.

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[25] *Barson By and Through Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832 (Utah 1984).

[26] *Price-Orem Inv. Co. v. Rollins, Brown & Gunnell, Inc.*, 713 P.2d 55, 59 (Utah 1986).

4. Breach of Express Warranty and Breach of Implied Warranty for Fitness

Plaintiff agrees that her claims for breach of express warranty and breach of implied warranty for fitness should be dismissed. Therefore, Defendants' Motion will be granted as to these two claims and they will be dismissed with prejudice.

5. Breach of Implied Warranty of Merchantability

To establish that there was a breach of an implied warranty of merchantability, Plaintiff must show that (1) Defendants sold a good, (2) which the Decedent bought, and (3) which did not meet one of the standards of merchantability—passes without objection; is of fair average quality; is fit for ordinary purposes; is of even kind, quality and quantity; is adequately contained, packaged and labeled; and conforms to promises on the packaging.[27]

Plaintiff alleges that Defendants' product was unmerchantable in that it was unfit for its ordinary purpose, was not of even quality, and was not adequately labeled. Though this claim is largely conclusory, it is based on the other allegations contained in the Complaint, which are sufficient to withstand dismissal. Therefore, this claim will not be dismissed.

6. Gross Negligence and Intentional Misconduct

"Gross negligence 'is the failure to observe even slight care; it is carelessness or recklessness to a degree that shows utter indifference to the consequences that may result.'"[28]

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[27]Utah Code Ann. § 70A–2–314.

[28]*Pearce v. Utah Athletic Found.*, 179 P.3d 760, 767 (Utah 2008) (quoting *Berry v. Great Park City Co.*, 171 P.3d 442, 449 (Utah 2007)).

"Intentional misconduct is similar in nature but requires Plaintiff[] to show not only indifference to the consequences, but actual intent."[29]

Plaintiff's Complaint states:

> In addition to the foregoing, the Mylan Defendants' conduct was of such a character and degree as to constitute willful, malicious, intentional misconduct and gross negligence. The Mylan Defendants had knowledge of the wrongfulness of the conduct and the high degree of probability that substantial injury or damage would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage. Moreover, the conduct of the Mylan Defendants was so reckless or wanting in care that it constituted a knowing and reckless indifference to the life, safety, or rights of persons exposed to such conduct.[30]

These allegations are simply too conclusory and unsupported to withstand a motion to dismiss. Therefore, these claims are dismissed without prejudice.

IV. CONCLUSION

It is therefore

ORDERED that Defendants' Motion to Dismiss (Docket No. 5) is GRANTED IN PART AND DENIED IN PART as set forth above.

DATED June 25, 2013.

BY THE COURT:

TED STEWART
United States District Judge

[29]*Stanley*, 2010 WL 3718589, at *5.

[30]Docket No. 1, ¶ 40.